K094042

JUN 30 2010

510(k) Summary
PEEK PREVAIL™ Cervical Interbody Device
June 29, 2010

I. **Company:**

Medtronic Sofamor Danek, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
(901) 396-3133

Contact:

Justine Viera
Regulatory Affairs Specialist
Telephone: (901) 399-2239
Fax: (901) 346-9738

II. **Proposed Proprietary Trade Name:** PEEK PREVAIL™ Cervical Interbody Device

III. **Classification Names(s):** Intervertebral Body Fusion Device

Class: II

Product Code(s): ODP

Regulation No.: 21 CFR 888.3080

IV. **Device Description:** The PEEK PREVAIL™ Cervical Interbody Device is an intervertebral body fusion device with internal screw fixation. The screws protrude through the interbody portion of the device and stabilize the vertebral body while preventing expulsion of the implant. The implant is "I-Beam" shaped with a 2 screw midline configuration. This device is intended to be radiolucent and the interior space of the product is to be used with bone graft.

The key difference between the predicate PEEK PREVAIL™ Cervical Interbody Device and the subject PEEK PREVAIL™ Cervical Interbody Device is the reduction of the device footprint by 2mm in the anterior/posterior dimension (i.e., adding a smaller footprint cage).

This product will be manufactured from PEEK Optima® and will have tantalum radiopaque markers and a nitinol screw locking mechanism. The screw designed to be used with this device will be manufactured from titanium alloy.

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V. **Indications for Use:** The PEEK PREVAIL™ Cervical Interbody Device is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The PEEK PREVAIL™ Cervical Interbody Device must be used with internal screw fixation provided by ZEPHIR® Anterior Cervical Screws. The PEEK PREVAIL™ Cervical Interbody Device implants are to be used with autograft and implanted via an open, anterior approach. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

VI. **Summary of the Technological Characteristics:** The subject device is the result of surgeon feedback where a device with a smaller footprint than the predicate device was desired in order to accommodate variations in patient anatomies. Table 1 summarizes the similarities between the predicate device and the subject device.

Table 1: Similarities between the Predicate device to Subject device

Predicate	Subject
Indications for Use/Intended Use	Identical
Levels of Attachment: Cervical C2-C3 to C7-T1	Identical
Material (PEEK)	Identical
Fundamental Scientific Technology	Identical
Surgical Technique – Anterior approach	Identical
Mating components: ZEPHIR® Anterior Cervical System screw	Identical
Sub-assembly components: Nickel Titanium alloy wire Tantalum radiopaque markers	Identical
Packaging	Identical
Sterilization method - Gamma	Identical

VII. **Identification of Legally Marketed Device(s):** Documentation was provided which demonstrated that the PEEK PREVAIL™ Cervical Interbody Device components are substantially equivalent to previously approved device PEEK PREVAIL™ Cervical Interbody Device (K073285, S.E. 05-15-2008).

VIII. **Discussion of the Non-Clinical Testing:** The following mechanical tests of the subject device were performed:

- Static axial torsion in accordance with ASTM F2077-03 "Test Methods for Intervertebral Body Fusion Devices," approved April 10, 2003. The acceptance criteria was/were met.

- Dynamic axial torsion in accordance with ASTM F2077-03 "Test Methods for Intervertebral Body Fusion Devices," approved April 10, 2003. The acceptance criteria was/were met.

IX. **Conclusions:** The subject device passed the mechanical testing in accordance with ASTM F2077-03 and was found to be safe and effective as compared to the predicate device PEEK PREVAIL™ Cervical Interbody Device (K073285, S.E. 05-15-2008).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medtronic Sofamor Danek, Inc.
% Ms. Justine Viera
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, TN 38132

SEP 12 2011

Re: K094042
Trade/Device Name: PEEK PREVAIL™ Cervical Interbody Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: April 27, 2010
Received: April 28, 2010

Dear Ms. Viera:

This letter corrects our substantially equivalent letter of June 30, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K094042

Device Name: PEEK PREVAIL™ Cervical Interbody Device

Indications for Use:

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Prescription Use ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
for Division of Surgical, Orthopedic,
and Restorative Devices

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